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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/571,285   | 03/09/2006  | Kenji Hayashi        | 1056-0134PUS1       | 8225             |
| 2292 7590 09/12/2008<br>BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      |                     |                  |
| EXAMINER<br>BLANCHI, KRISTIN A   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1626   |             |                      |                     |                  |
| NOTIFICATION DATE  |             | DELIVERY MODE        |                     |                  |
| 09/12/2008   |             | ELECTRONIC           |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

# Office Action Summary

**Application No.**

10/571,285

**Applicant(s)**

HAYASHI ET AL.

**Examiner**

KRISTIN BIANCHI

**Art Unit**

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date 03/09/2006 and 06/09/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-3 are pending in the instant application. Claims 1-3 are rejected.

#### ***Information Disclosure Statement***

The information disclosure statement filed March 9, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The three WIPO documents listed on the information disclosure statement have not been received. It has been placed in the application file, but the information referred to therein has not been considered.

#### ***Priority***

Applicants are claiming the benefit of foreign priority document 2003-318974 filed on September 10, 2003. However, an English copy of this document has not been received in this application. Therefore, this application will be given priority to PCT/JP04/12650 (filed on September 1, 2004) only.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

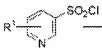
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haneda et al. (US 2002/0128480) in view of Owa et al. (Bioorganic and Medicinal Chemistry Letters 12 (2002) 2097-2100) and Crassier et al. (WO 02/059092) further in view of <http://en.wikipedia.org/wiki/Tetrahydrofuran>.

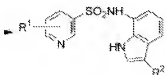
*Determination of the scope and contents of the prior art.*

Haneda et al. discloses the synthesis of 3-Cyano-N-(3-cyano-4-methyl-1H-indole-7-yl)benzenesulfonamide by dissolving 7-amino-3cyano-4-methyl-1H-indole in tetrahydrofuran, and then pyridine and 3-Cyanobenzenesulfonyl Chloride were added thereto (page 11, Example 1). Haneda et al. also discloses the production of 7-Amino-3cyano-4-methyl-1H-indole (page 8, Production Example 12) through the reduction of 3-Cyano-4-methyl-7-nitro-1H-indole (page 7, Production Example 6), which was made by dissolving 3-Formyl-4-methyl-7-nitro-1H-indole (i.e. which was made by adding phosphorus oxychloride in DMF to 4-Methyl-7-nitro-1H-indole in DMF, page 6, Production Example 5) in DMF and adding hydroxylamine hydrochloride and pyridine.

Owa et al. discloses the reaction of compound 6 (Scheme 1, page 2098) with



in pyridine and EtOAc to produce



Crassier et al. discloses (1) an indole ester of the formula II is formylated and that the formylation is particularly preferably carried out in DMF in the presence of POC13 (page 6, line 10), (2) the formyl ester of the formula III formed from (1) is reacted with hydroxylamine to give an oxime derivative of the formula IV and (3) the oxime of the formula IV is converted into a cyanoindole ester of the formula V (page 2, line 25 through page 3, line 25). Crassier et al. also discloses that in a particular embodiment of the process, steps (1) to (3) are carried out in situ, i.e. in a one-pot process (page 7, line 5) and that the one-pot process gives better yields compared with the stepwise synthesis.

<http://en.wikipedia.org/wiki/Tetrahydrofuran> discloses that THF tends to form peroxides on storage in air (i.e. under "Precautions").

Ascertaining the differences between the prior art and the claims at issue.

Haneda et al. discloses the synthesis of 3-Cyano-N-(3-cyano-4-methyl-1H-indole-7-yl)benzenesulfonamide in a different solvent (i.e. tetrahydrofuran) than the instant claims (i.e. a mixed solvent of water and C1-6alkyl acetate) although the base, reactant and product are exactly the same as the instant claims. Haneda et al. also discloses that the synthesis steps to make 3-Cyano-4-methyl-7-nitro-1H-indole are not carried out in situ although all the solvents, reagents, reactants and products are identical to those of the instant claims.

Owa et al. discloses the synthesis of the N-(7-Indolyl)-3-pyridinesulfonamide derivatives in a slightly different solvent (i.e. EtOAc) than the instant claims although the base, reactants and products are exactly the same.

Crassier et al. discloses the synthesis to make compounds of formula V (page 3, line 25) as a one-pot process and with the same solvents and reagents as the instant claims, however, the indole derivatives are slightly different structurally than those of the instant claims.

Resolving the level of ordinary skill in the pertinent art – Prima Facie Case of Obviousness.

It would have been obvious to one of ordinary skill in the art at the time of the invention to carry out the processes of the instant claims in view of the aforementioned references. It is common practice for a person skilled in the art to carry out a synthesis in different solvent conditions in an attempt to optimize a synthesis. Further, the courts have stated that changes in process conditions of an old process does not impart patentability in the absence of unexpected results. In re Boesch, 205 USPQ 215 (1980). In re Aller et al. (CCPA 1955) 220 F2d 454. In re Dunn, 146 USPQ 479 (i.e. use of a conventional solvent in an other wise known process is not a patentable modification). Also, it was known in the art at the time of the invention that THF, which is an ether, tends to form

peroxides, so carrying out the reaction in different solvents would have been obvious.

In regards to the one-pot synthesis of 3-Cyano-4-methyl-7-nitro-1H-indole, it would have been obvious to attempt to carry out this synthesis in a one-pot synthesis in view of Crassier et al.

One of ordinary skill would have reasonable expectation of success in practicing the instantly claimed processes. One would be motivated to carry out the instant processes in an attempt to find optimal conditions for carrying out a known process. Therefore, the instant claims are *prima facie* obvious.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KRISTIN BIANCHI whose telephone number is (571)270-5232. The examiner can normally be reached on Mon-Fri 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/571,285  
Art Unit: 1626

Page 6

/Kamal A Saeed, Ph.D./  
Primary Examiner, Art Unit 1626

Kristin Bianchi  
Examiner  
Art Unit 1626

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